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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,577	12/18/2000	Yosef ² Freedland	JST-14	6342

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EXAMINER

REIP, DAVID OWEN

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 04/24/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/740,577

Applicant(s)

FREEDLAND, YOSEF

Examiner

David O. Reip

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34,35,40,43,47-50 and 77-92 is/are pending in the application.
- 4a) Of the above claim(s) 78-81 and 89-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34,35,40,47-50,77 and 82-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly submitted claims 78-81 and 89-92 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 78-81 and 89-91 recite limitations not found in the elected invention of Group I, Species 11 of elongate fasteners (Fig. 73) in combination with Species 5 of collets (Fig. 67), such election having been made in paper #8.

Since applicant has received an action on the merits (paper #9) for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 78-81 and 89-92 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims 78-81 and 89-92 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

The amendment filed 3/17/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment

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shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the first two paragraphs added to the specification contain new matter directed to the definition of the area of the contact surface of the wing and the extent of the contact surface area as compared to the areas of adjoining surfaces. The original disclosure provides no written description of these areas and their relative sizes as compared to each other, and the simplified illustrations seen in Figs. 71-74, also part of the original disclosure, in no way provide enough detail of the wing element 11i1 to support the added material. Therefore, all such material constitutes new matter. Note also that all claims directed to the new matter are also objected to.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 34, 35, 40, 43, 47-50, 77, 82, and 84-88 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, with respect to claim 34, line 4, "a contact surface having a contact area *that contacts a portion of the bone,*" and line 6, "having a contact edge *that contacts the bone.*" constitute positive recitations of the bone. Human bone, being a part of the human body, is non-statutory subject matter (see notice below) and cannot be claimed. Claim

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82, line 4 also contains a positive recitation of bone, specifically "in which a surface of the wing *contacts a bone surface*."

Then Assistant Secretary and Commissioner of Patents and Trademarks, Donald J. Quigg, issued a notice in the Official Gazette stating, "A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution." 1077 OG 24 (1987), reprinted in 1146 TMOG 24 (1993).

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 34, 35, 40, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Dzus et al '531. Figs. 1-7 of Dzus et al show an orthopedic fastening system having all the limitations as recited in the above listed claims, including: an shaft 10; a wing 13 pivotally engaged (via hinge pin 14) at one end of the shaft and having a contact surface with at least two adjoining surfaces, the adjoining surfaces each having a contact edge for contacting bone; and an internally threaded "collet" 17. Note that the limitation "the contact surface has a greater area than any adjoining surface" is met in Dzus et al in that any discrete sections of the side portions of wing 13 can be defined as "adjoining surfaces," including sections having areas smaller than the area of the contact surface.

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Claims 34, 35, 40, 43, and 83-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Tennican (U.S. Pat. No. 3,168,850). Fig. 1 of Tennican shows a fastening system that is capable of being used as a bone fastener, the fastening system having all the limitations as recited in claims 34, 35, 40, 43, and 83-86, including: a shaft 20; a wing 10 pivotally engaged (via hinge pin 28) at one end of the shaft and having a contact surface with at least two adjoining surfaces (the "adjoining surfaces" comprising the narrow edge surfaces defined by the thickness between the inner concave surface and the outer convex surface of wing 10), the adjoining surfaces each having a contact edge for contacting bone; and an internally threaded "collet" 40. With respect to claim 83, note that the axis of hinge pin 28 is external to the contact surface of wing 10.

Claims 34, 40, 82, 83, and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferris (U.S. Pat. No. 4,865,501). Fig. 1 of Ferris shows a fastener system that is capable of being used as a bone fastener, the fastener system having all the limitations as recited in claims 34, 40, 82, 83, and 85, including: a shaft 21; a wing 13/15 pivotally engaged at one end of the shaft (via living hinge 17) and having a contact surface that lies in a plane defined by first and second "extents" (i.e. along the length and width); and a third "extent" (i.e. the thickness of wing 13/15), the third extent being smaller than either the first or second extent.

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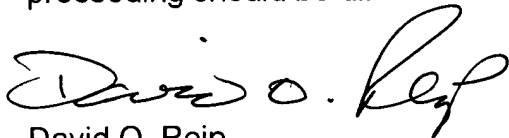
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Foerster, Jr (U.S. Pat. No. 5,226,767).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip at (703) 308-3383. The examiner can normally be reached Mon-Thu and every other Fri from 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano, can be reached at (703) 308-2496. The fax number for this Unit is (703) 308-2708 (unofficial) or (703) 872-9302 (official). The examiner can also receive direct-to-computer faxes at 703-746-3310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at (703) 308-0858.

A handwritten signature in black ink, appearing to read "David O. Reip". The signature is fluid and cursive, with the first name "David" being the most prominent part.

David O. Reip
Primary Examiner
April 21, 2003